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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/884,062 | 06/20/2001 | Herbert Lapidus | 364.31 | 1692 |

5514 7590 05/21/2003

FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

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| EXAMINER |
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YU, GINA C

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| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 05/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/884,062

Applicant(s)

LAPIDUS, HERBERT

Examiner

Gina C. Yu

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED on May 2, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ they raise the issue of new matter (see Note below);
(c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See continuation sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

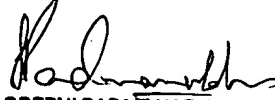
Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 1,3,4,7-10 and 13-30.

Claim(s) withdrawn from consideration: 1, 3, 4, 7-10, and 13-30.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____


SREENI PADMANABHAN
PRIMARY EXAMINER

5/16/03

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Continuation from No. 2:

The proposed amendments will not be entered because they do not place the application in a better form for appeal by materially reducing or simplifying the issues because the amendment and arguments do not overcome the obviousness rejections under 35 U.S.C. § 103 indicated in the previous Office action dated December 18, 2002. See below, No. 5.

Continuation from No. 5:

The request for reconsideration has been fully considered but does not place the application in allowable condition because applicants' arguments are not persuasive, and the obviousness rejections as indicated in the previous Office action dated December 18, 2002 are maintained.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the rejections are based on combination of references which teach that hemorrhoid foam and aerosols, foam formulation for personal cleansing products, and mild surfactants used for baby wipe products are well known in the art.

Specifically, applicants argue that the Singh reference fails to teach foam formulation and using a disposable substrate. In response, examiner reiterates that Singh suggests to formulate the hemorrhoidal application in the form of foam. The

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specific foam formulations for personal cleansing composition - water, surfactants, foam stabilizer, and humectants - contained in a manually actuated pump are taught in Fowler. The reference also teaches using the product with a substrate such as sponge or washcloths. While applicants argue that these substrates are not disposable like applicants' bathroom tissue, examiner takes the position that there is no evidence in the record that the suggested substrates are limited to non-disposable products. Examiner also asserts that the use of disposable substrate for baby wipes as taught in Pregozen renders the similar usage for adults obvious. It would have been obvious to substitute one form of substrate with another that serves the same purposes.

In response to applicants' argument that the Fowler invention requires rinsing with water, examiner asserts that the Fowler is cited to show the conventional basic formulation and structure of a personal cleansing foam. The specific surfactant-base for a baby wipe product is taught in Pregozen. Applicants' argument that the Fowler invention is concerned with skin or hair and not mucosal areas is unpersuasive, as the Pregozen reference shows that a routineer would have known the specific mild surfactants suitable to use to cleanse vaginal or anal areas.

Applicants also argue that Pregozen should be distinguished because the reference relates to moistened or impregnated non-woven substrates. Examiner notes that the practice of dispensing foam from a manual pump on a substrate for personal cleansing purposes is well known in the art, as shown by Fowler. In response to applicants' argument that the Pregozen and Fowler references are not related,

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examiner asserts that both inventions are personal cleaning products and are relevant to each other and to the present invention.

In response to applicants' argument that Jorgensen is directed to a skin cleanser, examiner asserts that in view of Pregozen it would have been obvious to the routineer that the mild detergent in the Jorgensen invention would be suitable for cleansing vaginal or anal area. Applicants' argument that the each prior art requires the ingredients other than those recited components is unpersuasive, since the inventions in claims 26-28 are compositions "comprising" water, surfactants, and foam stabilizing agent, and are open to include other elements not recited in the claims.

While applicants assert that the present invention provides the foam that retains its integrity which does not moisten the disposable substrate and collapses only when applied to the vaginal or anal area, examiner views that the a composition meeting the recited limitation would obviously possess such properties.

Applicants also argue that the phrase "suitable for use as a vaginal or hemorrhoidal wipe" should be given patentable weight. Examiner respectfully disagrees. It is well settled in patent law that "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claimed limitation." See Rowe v. Dror, 112 F.3d 473, 478, 42 U.S.P.Q. 2d 1550, 1553 (Fed. Cir. 1997). The court in Kropa v. Robie also held that preamble is not a limitation where claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim. See 187 F.2d at 152, 88 U.S.P.Q. 2d at 480-81. In this

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case, examiner takes the position that the phrase does not set structural limitation. The composition in the claims requires surfactants, water, foam stabilizing ingredients, and additives. The term "suitable for use as a vaginal or hemorrhoidal wipe" is not essential to define the invention comprising the said components. Even if read in the context of the entire claim, the preamble recitation is merely states the intended use of the invention or property inherent to the prior art composition comprising same components, and no other distinct definition of any of the limitation. While applicants assert that not every combination of water, surfactant and foam stabilizer would be suitable for the vaginal or hemorrhoidal wipe, there is no evidence in the record to show that the Vinski composition for skin cleansing somehow is not suitable for the recited use. Examiner maintains the position that the phrase "suitable for use as a vaginal or hemorrhoidal wipe" is deemed as a recitation of an intended use of the claimed product, and not given patentable weight.

Applicants' argument that two specific foam densifying agents used in the example formulation in the Vinski composition materially affects the novelty of the composition is unpersuasive. Specifically, applicants argue that a C8-12 acyl lactylate and an ethoxylated glyceride ester are necessary ingredients for the prior art and assert that only the formulation comprising these ingredients render completely satisfactory results, whereas other examples lacking these components have some deficiency. Examiner finds the argument unpersuasive, because the Vinski reference as whole teaches that the novelty of the invention attributes to the combination of an anionic surfactant and the specific amphoteric surfactants described in col. 1, line 53 – col. 2,

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line 26. Examiner notes that the reference does suggest adding the foam densifying agents in col. 4, lines 55 – col. 65. However, examiner views that it is improper to consider these ingredients as required essential element in the prior art. It is noted that the data of Examples 1-26 does indicate compositions having the both foam densifying agents provide denser foam. However, examples 14-16 and 18-21 indicate that using only one of the foam densifying agent or neither still produces good lather. Examiner views that the exclusion of the foam densifying agent would have been an option for a skilled artisan who desires a less dense foam composition, and not a required essential element in the Vinski invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

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Gina C. Yu
Patent Examiner
May 16, 2003